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SAOUD, CHRISTINE J

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1647
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Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|--------------------------------------|---------------------------------------|
| Office Action Summary | Application No. 09/907,007 | Applicant(s) HAYWARD et al. |
| | Examiner Christine Saoud | Art Unit 1647 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Jan 21, 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 43-68 is/are pending in the application.

4a) Of the above, claim(s) 43-58 and 61-68 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 59 and 60 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on Jul 17, 2001 is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. 08/765,588.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6

6) Other:

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group VII in Paper No. 10 is acknowledged. The traversal is on the ground(s) that the inventions are not both "independent and distinct". This is not found persuasive because MPEP 802.01 makes clear the meaning of "independent and distinct" in terms of proper restriction practice. The 1952 Patent Act and states "[t]he law has long been established that dependent inventions ... may be properly divided if they are, in fact, "distinct" inventions, even though dependent" (see last sentence of MPEP 802.01). In summary of the interpretation of "independent and distinct" as used in 35 U.S.C. 121, MPEP 803 defines a restriction to be proper between two or more inventions "only if they are able to support separate patents and they are either independent or distinct" (emphasis added). Therefore, the restriction set forth in paper #8 did not need to show both independence and distinction according to MPEP 803. An application may properly be required to be restricted to one of two or more claimed invention if they are able to support separate patents and they are either independent (MPEP § 806.04 - § 806.04 (j)) or distinct (MPEP § 806.05 - § 806.05(i)). The Examiner has shown that the inventions of Groups I-XI are distinct for the reasons in the previous Office action (see paper #8). Applicant has offered no evidence to rebut this showing. Applicant's statements regarding filing costs, the classification system and legal challenges are noted but are not persuasive as they fail to indicate the error in the restriction requirement.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 43-68 are pending in the instant application. Claims 43-58 and 61-68 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10. Claims 59-60 are under examination in the instant application.

Drawings

3. Figure 8 of the instant application is presented on separate pages. Although Figures 8A and 8B are correctly labeled according to 37 C.F.R. § 1.84 (U)(1), which requires that when partial views of a drawing which are intended to form one complete view must be identified by the same number followed by a capital letter, the Brief Description of the Drawings at page 10 does not properly refer to the Figures, in that lower case letters are used. Correction is required.

Figures 1-6, 9-11, and 16-17 of the instant application are presented in separate panels or on separate pages. 37 C.F.R. § 1.84(u) (1) states that when partial views of a drawing which are intended to form one complete view, whether contained on one or several sheets, must be identified by the same number followed by a capital letter. The instant application uses the format of a number followed by lower case roman numerals. Applicant is reminded that once the drawings are changed to meet the separate numbering requirement of 37 C.F.R. § 1.84(u) (1), the specification should be amended to change the Brief Description of the Drawings and the rest of the specification accordingly. If, for example, Figure 1 is divided into Figures 1A, 1B, 1C, and

1D, then the Brief Description and all references to this figure in the specification must refer to Figures 1A, 1B, 1C and/or 1D.

Specification

4. The disclosure is objected to because of the following informalities: the filing date for application Serial Number 08/765,588 is incorrect in the first line of the specification. The date is listed as February 22, 996, however, a 371 application is only given a filing date when all of the requirements of 371 are met. These requirements were fulfilled on 4/25/97, and therefore, this is the filing date for the 08/765,588 application.

Appropriate correction is required.

5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 59-60 are provisionally rejected under the judicially created doctrine of double patenting over claims 47 and 52 of copending Application No. 08/765,588. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the claims of '588 are directed to nucleic acids which comprise or consist of SEQ ID NO:3. The instant claims are to nucleic acids which hybridize to SEQ ID NO:3. The most obvious embodiment of the broader claims would be the nucleic acid of SEQ ID NO:3, therefore, the claims of '588 and the instant claims are directed to common subject matter and issuance of a patent to both would provide an improper extension of the "right to exclude" granted by a patent.

8. Claims 59-60 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 46 of copending Application No. 09/349,954. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to nucleic acid molecules encoding polypeptides, and the claims of '954 are directed to methods of making polypeptides using specific nucleic acid molecules. Such method claims of '954 were not restricted from the nucleic acid claims and it is *prima facie* obvious to use the nucleic acid which encodes the polypeptide in a method of making the polypeptide. The nucleic acids of the instant application are encompassed and used by the method claims of '954, therefore, the subject matter clearly overlaps and is not patentably distinct, absent evidence to the contrary.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 59-60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite that the nucleic acids encode "VEGF-B". The

specification does not disclose “VEGF-B”, and therefore, a claim to a nucleic acid which encodes “VEGF-B” is new matter.

11. Claims 59-60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 59-60 are directed to nucleic acids which hybridize to SEQ ID NO:3 under specific conditions (no wash conditions provided), wherein the nucleic acid encodes a “VEGF-B molecule”. In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant has possession of a nucleic acid molecule which has the sequence of SEQ ID NO:3 and this nucleic acid molecule encodes a polypeptide. The subject matter which is claimed is described above. First, a determination of the level of predictability in the art must be made in that whether the level of skill in the art leads to a predictability of structure; and/or whether teachings in the application or prior art lead to a predictability of structure. The claims are directed to nucleic acids which hybridize to SEQ ID NO:3 under specific conditions (no wash conditions provided), wherein the nucleic acid encodes a “VEGF-B molecule”. First, the claims are not limited to nucleic acids which encode a particular protein, but possibly a class of proteins. The instant specification fails to define what is encompassed by “VEGF-B molecule” as the term is not mentioned anywhere in the description. The claims only require the nucleic acid molecule

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hybridize to SEQ ID NO:3 and encode a “VEGF-B molecule”. The specification describes a VEGF molecules from two species, including splice variants, but fails to describe what is intended by “VEGF-B molecule”. The claims do not recite any functional characteristics or the full conditions to be used in the hybridization procedure, which would include the wash conditions. The breadth of the claims is such that the claims encompass nucleic acids encoding polypeptides from other species, nucleic acids encoding polypeptides which are variants, nucleic acids encoding other VEGF-like molecules (possibly, since there is no definition of “VEGF-B” in the specification). There is a lack of guidance or teaching regarding structure and function because there is only a single example provided in the specification and because there is no guidance found in the prior art. The claims include molecules which share some sequence similarity to the disclosed molecules (by recitation of hybridizing), however, this sequence similarity is not sufficient to provide the function of encoding a polypeptide a VEGF-B molecule, absent evidence to the contrary.

Next in making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, each claimed species and genus must be evaluated to determine whether there is sufficient written description to inform a skilled artisan that applicant was in possession of the claimed invention at the time the application was filed. With this regard, the instant application fails to provide a written description of the species or the genus which are encompassed by the instant claims except for the nucleic acid of SEQ ID NO:3. The specification does not provide a complete structure of those polynucleotides which encode a polypeptide as described in the claims and hybridize to the recited sequence under the recited

stringency conditions of the claims. The claims also fail to recite other relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure) sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. The specification fails to provide a representative number of species for the claimed genus (those polynucleotides which hybridize to SEQ ID NO:3 under the recited stringency conditions) because the claims are directed to those polynucleotides which encode a VEGF-B molecule, with no definition of what is encompassed by “VEGF-B molecule”. Therefore, the claims are directed subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath In. v. Mahurkar, 19 USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for the purposes of the ‘written description’ inquiry, whatever is now claimed.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (see *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is

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required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to a lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated the nucleic acid of SEQ ID NO:3, but not the full breadth of the claim meets the written description provision of 35 U.S.C. § 112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

12. Claims 59 and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 59 and 60 are directed to nucleic acid molecules encode a “VEGF-B molecule”. However, the metes and bounds of this term cannot be determined since the instant specification never mentions this term and therefore, does not define the metes and bounds of this term. The specification refers to the protein encoded by SEQ ID NO:3 as “VEGF-like”, but the specifics of what constitutes this protein from other VEGF or VEGF-like molecules is not indicated. The specification contemplates molecules having “at least 15% similarity” and “at least 30% dissimilarity”, but again, this does not provide the metes and bounds of what a “VEGF-B” protein

is to the exclusion of other VEGF molecules. The specification does not provide an assay to distinguish a "VEGF-B" protein from other VEGF molecules, there is no structure that is unique to "VEGF-B" to the exclusion of other VEGF molecules, and therefore, one of ordinary skill in the art would not recognize a "VEGF-B" from other VEGF molecules because the metes and bounds of "VEGF-B" are indefinite.

Claims 59 and 60 are also directed to molecules which "hybridize under high stringency conditions to SEQ ID NO:3", however, the conditions for hybridization are not complete. Nucleic acid molecules will hybridize (or stick) to another nucleic acid molecule under particular conditions. The conditions under which they initially stick may vary in stringency, which governs how many nucleotides are involved in the sticking process. However, once the two nucleic acid molecules are hybridized (or stuck together), the complex is washed, which removes those nucleic acid molecules which do not hybridize, or have hybridized but only weakly. It is these wash conditions which also contribute to the stringency of the hybridization because it is the wash which determines which nucleic acids remain stuck to the test nucleic acid molecule. Therefore, there are a number of wash conditions which could be used for the given "high stringency conditions", and without knowing which wash conditions are to be used, the claims are indefinite because the metes and bounds of "high stringency" cannot be determined.

13. Claims 59-60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are directed to nucleic acid molecules which hybridize to SEQ ID NO:3 and encode a “VEGF-B molecule”. However, SEQ ID NO:3 is a coding strand of DNA, therefore, molecules which hybridize to this coding strand would, by definition, be non-coding material. Therefore, it is not possible for the non-coding material to encode a “VEGF-B molecule” unless the nucleic acid codes for the protein in both directions. The instant specification fails to teach that this is property of the nucleic acids which would hybridize, and therefore, the specification is not enabled for a nucleic acid molecule which hybridizes to SEQ ID NO:3 and encodes a “VEGF-B molecule”.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 59-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Tischer et al. (U.S. Pat. No. 5,194,596).

Tischer et al. teach a nucleic acid molecule which encodes a VEGF protein (see Figure 7). Figure 7 of Tischer et al. teaches a nucleic acid molecule which has 68% similarity to SEQ ID NO:3 of the instant application over a span of 174 nucleotides. It would appear that this molecule would hybridize to the nucleic acid of SEQ ID NO:3, and therefore, would meet the structural limitations of the claims. Tischer et al. do not describe this molecule as encoding a “VEGF-B

molecule", but in light of the lack of a definition of this term in the instant specification, it would appear that any molecule which would hybridize under the recited conditions would therefore encode a "VEGF-B molecule. The nucleic acid molecule of Tischer et al. therefore anticipates the instant claims.

Conclusion

16. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Christine J. Saoud, Ph.D., whose telephone number is (703) 305-7519. The Examiner can normally be reached on Monday to Thursday from 8AM to 2PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. §§ 1.6(d) and 1.8). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternate number. Official papers filed After Final rejection filed by fax should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

**CHRISTINE J. SAoud
PRIMARY EXAMINER**

(Christine J. Saoud)